

## § 173.40

(d)(1) The ion-exchange resins identified in paragraphs (a)(1), (a)(2), (a)(11), and (a)(15) of this section are exempted from the acetic acid extraction requirement of paragraph (c)(4) of this section.

(2) The ion-exchange resin identified in paragraph (a)(20) of this section shall comply either with:

(i) The extraction requirement in paragraph (c)(4) of this section by using dilute sulfuric acid, pH 3.5 as a substitute for acetic acid; or

(ii) The extraction requirement in paragraph (c)(4) of this section by using reagent grade hydrochloric acid, diluted to pH 2, as a substitute for acetic acid. The resin shall be found to result in no more than 25 parts per million of organic extractives obtained with each of the following solvents: Distilled water; 15 percent alcohol; and hydrochloric acid, pH 2. Blanks should be run for each of the solvents, and corrections should be made by subtracting the total extractives obtained with the blank from the total extractives obtained in the resin test.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter.

[42 FR 14526, Mar. 15, 1977, as amended at 46 FR 40181, Aug. 7, 1981; 46 FR 57033, Nov. 20, 1981; 49 FR 28830, July 17, 1984; 56 FR 16268, Apr. 22, 1991; 62 FR 7679, Feb. 20, 1997; 64 FR 14609, Mar. 26, 1999; 64 FR 56173, Oct. 18, 1999]

## § 173.40 Molecular sieve resins.

Molecular sieve resins may be safely used in the processing of food under the following prescribed conditions:

(a) The molecular sieve resins consist of purified dextran having an average molecular weight of 40,000, cross-linked with epichlorohydrin in a ratio of 1 part of dextran to 10 parts of epichlorohydrin, to give a stable three dimensional structure. The resins have a pore size of 2.0 to 3.0 milliliters per gram of dry resin (expressed in terms of water regain), and a particle size of 10 to 300 microns.

(b) The molecular sieve resins are thoroughly washed with potable water prior to their first use in contact with food.

(c) Molecular sieve resins are used as the gel filtration media in the final pu-

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rification of partially delactosed whey. The gel bed shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent microbial build-up on the bed and adulteration of the product.

## § 173.45 Polymaleic acid and its sodium salt.

Polymaleic acid (CAS Reg. No. 26099-09-2) and its sodium salt (CAS Reg. No. 70247-90-4) may be safely used in food in accordance with the following prescribed conditions:

(a) The additives have a weight-average molecular weight in the range of 540 to 850 and a number-average molecular weight in the range of 520 to 650, calculated as the acid. Molecular weights shall be determined by a method entitled "Determination of Molecular Weight Distribution of Poly(Maleic) Acid," March 17, 1992, produced by Ciba-Geigy, Inc., Seven Skyline Dr., Hawthorne, NY 10532-2188, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Product Policy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or are available for inspection at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b) The additives may be used, individually or together, in the processing of beet sugar juice and liquor or of cane sugar juice and liquor to control mineral scale.

(c) The additives are to be used so that the amount of either or both additives does not exceed 4 parts per million (calculated as the acid) by weight of the beet or cane sugar juice or liquor process stream.

[51 FR 5315, Feb. 13, 1986, as amended at 61 FR 386, Jan. 5, 1996]

## § 173.50 Polyvinylpyrrolidone.

The food additive polyvinylpyrrolidone may be safely used in accordance with the following prescribed conditions:

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(a) The additive is a homopolymer of purified vinylpyrrolidone catalytically produced under conditions producing polymerization and cross-linking such that an insoluble polymer is produced.

(b) The food additive is so processed that when the finished polymer is refluxed for 3 hours with water, 5 percent acetic acid, and 50 percent alcohol, no more than 50 parts per million of extractables is obtained with each solvent.

(c) It is used or intended for use as a clarifying agent in beverages and vinegar, followed by removal with filtration.

**§ 173.55 Polyvinylpyrrolidone.**

The food additive polyvinylpyrrolidone may be safely used in accordance with the following prescribed conditions:

(a) The additive is a polymer of purified vinylpyrrolidone catalytically produced, having an average molecular weight of 40,000 and a maximum unsaturation of 1 percent, calculated as the monomer, except that the polyvinylpyrrolidone used in beer is that having an average molecular weight of 360,000 and a maximum unsaturation of 1 percent, calculated as the monomer.

(b) The additive is used or intended for use in foods as follows:

Food	Limitations
Beer .....	As a clarifying agent, at a residual level not to exceed 10 parts per million.
Flavor concentrates in tablet form .....	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Nonnutritive sweeteners in concentrated liquid form .	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good manufacturing practice.
Nonnutritive sweeteners in tablet form .....	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vitamin and mineral concentrates in liquid form ....	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good manufacturing practice.
Vitamin and mineral concentrates in tablet form ....	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vinegar .....	As a clarifying agent, at a residual level not to exceed 40 parts per million.
Wine .....	As a clarifying agent, at a residual level not to exceed 60 parts per million.

**§ 173.60 Dimethylamine-epichlorohydrin copolymer.**

Dimethylamine-epichlorohydrin copolymer (CAS Reg. No. 25988-97-0) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is produced by copolymerization of dimethylamine and epichlorohydrin in which not more than 5 mole-percent of dimethylamine may be replaced by an equimolar amount of ethylenediamine, and in which the mole ratio of total amine to epichlorohydrin is approximately 1:1.

(b) The additive meets the following specifications:

(1) The nitrogen content of the copolymer is 9.4 to 10.8 weight percent on a dry basis.

(2) A 50-percent-by-weight aqueous solution of the copolymer has a minimum viscosity of 175 centipoises at 25 °C as determined by LVT-series Brookfield viscometer using a No. 2 spindle

at 60 RPM (or by another equivalent method).

(3) The additive contains not more than 1,000 parts per million of 1,3-dichloro-2-propanol and not more than 10 parts per million epichlorohydrin. The epichlorohydrin and 1,3-dichloro-2-propanol content is determined by an analytical method entitled "The Determination of Epichlorohydrin and 1,3-Dichloro-2-Propanol in Dimethylamine-Epichlorohydrin Copolymer," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(4) Heavy metals (as Pb), 2 parts per million maximum.

(5) Arsenic (as As), 2 parts per million maximum.